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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,987	05/30/2001	Gregory D. Plowman	038602-1180	6720

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,987	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 9-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The preliminary amendment filed October 3, 2001 amending the specification to insert reference to the sequence identifiers has been entered.

Claims 1-32 are pending.

Election/Restriction

Applicant's election with traverse of Group 8, claims 6-8, drawn to protein phosphatase of SEQ ID NO:8, in Paper No. 13 filed January 23, 2003 is acknowledged. The traversal is on the ground(s) that "Applicants respectfully disagree with the Examiner's rationale for requiring restriction between the amino acid of SEQ ID NO:8 and the nucleic acid encoding the protein phosphatase of SEQ ID NO:8 (Group 3). It is believed that the subject matter of the claims of Groups 3 and 8 are sufficiently related to be examined together, and such examination would not place an undue burden to the Examiner" (Response, page 2). This is not found persuasive because proteins and nucleic acids are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule can be used for the production of an encoded enzyme and as a hybridization probe. An enzyme can be obtained by a materially different method such as by the biochemical purification. Furthermore, the examination of nucleic acids with proteins would require a diverse consideration and an additional search of at least 435/252.3, 320.1; 536/23.2.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 9-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups 1-7 and 9-30, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 46, lines 17, 22, 27; page 49, line 23; page 107, line 11; page 109, lines 7,12, 20; page 113, line 13; page 127, lines 18-19, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because it is unclear what "Flv" stands for in Tables 1-4.

Claim Objections

Claims 6-8 are objected to under 37 CFR 1.75(d)(1) as being in improper form because the claim states an improper Markush group. Compounds included within a Markush group must (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility (See MPEP 803.02.) Proteins having the amino acid sequences of SEQ ID NOs:6-10 do not meet these requirements. They

are proposed to have different phosphatase functions and they have different structures. Considering that SEQ ID NOs:6-10 may share the common utility of being phosphatase, the specification does NOT disclose that the compounds share a substantial structural feature disclosed as being essential to that utility. Because a substantial structural feature is not disclosed as being essential to the utility that is common to the claimed species, the claim states an improper Markush group.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 6-8 are directed to a phosphatase polypeptide. Applicants disclose a human nucleic acid sequence of SEQ ID NO: 3 encoding the full length protein having the amino acid sequence of SEQ ID NO:8. The asserted utility for SEQ ID NO:8 is based on its classification as serine/threonine phosphatase (page 54, line 8, through page 55, line 8; Table 4) and further on its classification as PP2C (Tables 1-3; page 119, line 17, through page 120, line 2). This classification is based on 89% identity

over 449 amino acids with mouse putative PP2C (GenBank GI 12850332) (page 119, lines 17-19). The sequence search performed at the PTO reveals that GI 12850332 has 87.3% homology to SEQ ID NO: 8 and 74.4% homology to SEQ ID NO:3. However, GenBank GI 12850332 entry was replaced by a newer version GI 26378394 that defines th polypeptide as unnamed protein product. The sequence search performed at the PTO did not reveal any homology between SEQ ID NO:8 and a protein for which PP2C activity was demonstrated. At most, SEQ ID NO:8 has some sequence homology to putative or probable PP2Cs which not necessarily have the PP2C activity. There is no additional data to support any function for the protein of SEQ ID NO:8.

Even accepting the plausible utility of being a PP2C, one of ordinary skill in the art would not know which peptide is a substrate for the enzyme. Humans produce many isoforms of PP2Cs and each isoform of PP2C is expected to have a specific substrate(s) and function. The specification does not disclose a specific function of the polypeptides of SEQ ID NO: 8, its relationship to any disease, or any specific real world use. The specification describes generic functions for the protein and nucleic acid. It appears that the main utility of the polypeptide of SEQ ID NO:8 is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of

use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following rejections would apply even if the utility for a polypeptide of SEQ ID NO:8 would have been established.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6(a) is drawn to a phosphatase of any type having an amino acid sequence that is at least 90% identical to SEQ ID NO: 8. Therefore, the claim encompasses a genus of naturally-occurring and man made phosphatases that are widely different in function. Phosphatases include alkaline and protein phosphatases. The later comprises various types such as 1 and 2 and subtypes such as A, B, C and various isoforms thereof. The specification fails to provide the correlation between the structure and specific phosphatase function common to all members of the genus. Furthermore, claim 6(b) is drawn to a phosphatase of any type that lacks some domains of SEQ ID NO:8. Since there is no limitation on the structure of the claimed phosphatase in terms of its homology to SEQ ID NO:8, this amounts to any structure. The specification does not contain any disclosure of the function of all the polypeptide sequences derived from SEQ ID NO:8. The specification does not contain any disclosure of the function of all the modified polypeptide sequences derived from modified SEQ ID NO:8. The genus of polypeptides that comprise the above polypeptides is a large variable genus with the potentiality of exhibiting various activities. Therefore many functionally unrelated polypeptides are encompassed within

the scope of these claims. The specification discloses only a single species of the claimed genus, SEQ ID NO:8, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Claim 7 is drawn to a phosphatase isolated from a mammal. The recitation of "mammal" fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The specification discloses a single representative species of this diverse genus, a human phosphatase of SEQ ID NO:8. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "In claims to genetic material, however a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA", without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus". Similarly with the claimed genus of proteins the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

Claim 8 depends from claim 7 and is drawn to a phosphatase isolated from a human. Allelic variations and splicing variants of human proteins are very common. The claimed genera include species which are variant in function having amino acid sequences with at least 90% identity to SEQ ID NO:8 or having undisclosed homology to SEQ ID NO:8. Allelic variants encompass polypeptides whose function may or may not be altered relative to the function of a polypeptide of SEQ ID NO:8. The claimed genera are functionally diverse as they encompass polypeptides encoded by the same gene or different genes.

There is no description in the specification of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO:8 relates to the structure of any naturally occurring alleles as well no disclosure of any function for naturally occurring variants. The general knowledge in the art concerning alleles dose not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art structure of one does not provide guidance to the structure of others.

As such, the description of the structure and function of SEQ ID NO:8 and a DNA encoding thereof of SEQ ID NO:3 is insufficient to be representative of the attributes and features of the claimed genera.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a PP2C of SEQ ID NO:8, does not reasonably provide enablement for a phosphatase of any type having an amino acid sequence that is 90% identical to SEQ ID NO:8 or for a PP2C or any phosphatase having undisclosed homology to SEQ ID NO:8.The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of SEQ ID NO:8 resulting in any type of phosphatase activity because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide of the instant invention; (B) the general tolerance of said polypeptide

to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide structure having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6, with dependent claims 7 and 8, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "N terminal domain, a C terminal catalytic domain, a catalytic domain, a C terminal domain", etc. The specification provides general discussion of said terms and does not define them in relation to SEQ ID NO:8 (page 10, line 3,

through page 12, line 14). Furthermore, it is unclear what is the difference among "a C terminal catalytic domain, a catalytic domain, a C terminal domain". Therefore, without knowing which fragments of SEQ ID NO:8 are encompassed, it is impossible to know the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al.

Hillier et al. (1997, GenBank accession AA292266) teach a 547 bp mRNA "similar to PP2C". It has 99.8% identity to nucleotides 792-1339 of SEQ ID NO:3.

This EST is a fragment of human mRNA encoding a portion of a human protein. Therefore, it would have been obvious to one of ordinary skill in the art to use this EST to produce the encoded PP2C polypeptide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is

(703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

March 17, 2003